MAR 1 1 2014

510(k) Summary	
510(k) Number	K140327
Submitter Information:	
Date Prepared:	March 6, 2014
Submitter Name & Address:	St. Jude Medical 5050 Nathan Lane Plymouth, MN 55442
Contact Person:	Loucinda Bjorklund Principal Regulatory Affairs Specialist Phone (651) 756-3230 Fax (651) 756-5744 PMehta@sjm.com
Device Information:	
Trade Name:	Ultimum™ EV Hemostasis Introducer
Common Name:	Catheter Introducer
Class	II
Classification Name:	870.1340 Catheter introducer
Predicate Device:	Ultimum EV Hemostasis Introducer (K023447)
Device Description:	The Ultimum™ EV Hemostasis Introducer consists of a polyethylene introducer and dilator with a radiopaque marker band at the distal end. The introducer is fitted with a hemostasis valve for use during catheter introduction and/or exchange over a guidewire. The hub is located on the proximal end of the introducer, where a sideport with a three-way stopcock is provided for aspiration, fluid infusion, blood sampling, and pressure monitoring. The dilator is tapered at the distal tip with an internal lumen designed to accept guidewires that have a maximum diameter of 0.035" (0.889 mm).
Intended Use: (Indications for Use)	Ultimum EV Hemostasis Introducers are designed for the introduction of angiographic catheters, closed end catheters, balloon catheters and electrodes into a vessel where minimizing blood loss is essential.
Comparison to Predicate Devices	The modified Ultimum EV Hemostasis Introducer has the same intended use and fundamental scientific technology as the predicate device. The modified Ultimum EV has a redesigned hemostasis seal, minor dimensional and polymer material changes on the introducer hub assembly, and the use of an adhesive to bond the extension tube to the hub. The dilator packaged with the modified Ultimum EV is yellow. In addition, the modified Ultimum EV packaging is a PVC tray placed into a pouch. The technological characteristics of the modified Ultimum EV Hemostasis Introducer are substantially equivalent to the predicate device including packaging, biocompatibility, sterilization, and labeling. Biocompatibility and bench performance testing demonstrated that the subject device is substantially equivalent to the predicate device.

Summary on Non-Clinical Testing	Performance bench testing and biocompatibility testing were performed to verify the device modifications met the pre-determined acceptance criteria. The following performance bench tests were performed: • Sheath Configuration; Device Outer Diameter (OD) • Effective Sheath Length • Dilator Configuration; Dilator Sheath ID • Hemostasis Maintenance; Introducer Assembly • Clot Management; Flushing • Assembly (Kink Resistance) • Insertion (Kink Resistance) • Functional Use During Procedure • Tip Integrity • Suture Ring • Seal Performance; Device Exchange • Device Integrity; Hemostasis Sheath Break Force • Device Integrity; Dilator Sheath Break Force • Device Integrity; Hemostasis Hub and Aspiration Tube Break Force • Device Integrity; Hub and Cap Break Force • Dilator Flushing • Device Compatibility; Sheath Hub • Device Compatibility; Dilator Hub ID Biocompatibility testing was performed in accordance with ISO 10993-1, the devices were tested for cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity (acute), pyrogencity, hemocompatibility and chemical characterization. The results of the non-clinical data demonstrates that the subject device has met the acceptance criteria for performance bench testing and biocompatibility.
Statement of Equivalence	The modified Ultimum EV Hemostasis Introducer has the same indications for use and technological characteristics as the predicate device. Based on this and the data provided in this pre-market notification, the subject device and predicate device has been shown to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 11, 2014

St. Jude Medical
Loucinda Bjorklund
Sr. Regulatory Affairs Specialist
5050 Nathan Lane N
Plymouth, MN 55442

Re: K140327
Trade/Device Name: 19F Ultimum EV Hemostasis Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: February 7, 2014
Received: February 10, 2014

Dear Ms. Bjorklund,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K140327

Device Name: Ultimum EV Hemostasis Introducer

Indications for Use:

Ultimum EV Hemostasis Introducers are designed for the introduction of angiographic catheters, closed end catheters, balloon catheters and electrodes into a vessel where minimizing the blood loss is essential.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)